DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

November 6, 2015

KCI USA Incoprorated
Ms. Melanie Avila
Senior Manager, Regulatory Affairs
6203 Farinon Drive
San Antonio, Texas 78249

Re: K150006
Trade/Device Name: Prevena Incision Management System
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered suction pump
Regulatory Class: Class II
Product Code: OMP
Dated: October 12, 2015
Received: October 13, 2015

Dear Ms. Avila:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150006

Device Name
Prevena Incision Management System

Indications for Use *(Describe)*
The Prevena Incision Management System is intended to manage the environment of surgical incisions that continue to drain following sutured or stapled closure by maintaining a closed environment and removing exudate via the application of negative pressure wound therapy.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY
Prevena Incision Management Peel & Place Dressing and Customizable Dressing

Submitter Information [21 CFR 807.929(a)(1)]	
Name	KCI USA, Inc. (Kinetic Concepts, Inc.)
Address	6203 Farinon Drive San Antonio, TX 78249
Phone number	210-515-4059
Fax number	210-255-6727
Establishment Registration Number	3009897021
Name of contact person	Melanie Avila, Senior Manager, Regulatory Affairs
Date prepared	October 12, 2015
Name of the device [21 CFR 807.92(a)(2)]	
Trade or proprietary name	Prevena™ Incision Management System
Common or usual name	Negative Pressure Wound Therapy System
Classification name	Negative Pressure Wound Therapy Powered Suction Pump (and components)
Classification panel	General and Plastic Surgery
Regulation	878.4780
Product Code(s)	OMP
Legally marketed device(s) to which equivalence is claimed [21 CFR 807.92(a)(3)]	Prevena™ Incision Management System, cleared under 510(k) K121883
Device description [21 CFR 807.92(a)(4)]	Negative pressure wound therapy system
Indications for use [21 CFR 807.92(a)(5)]	The Prevena™ Incision Management System is intended to manage the environment of surgical incisions that continue to drain following sutured or stapled closure by maintaining a closed environment and removing exudate via the application of negative pressure wound therapy.

Comparison of the Technological Characteristics with the Predicate Device [21 CFR 807.92(a)(6)]

Negative Pressure Wound Therapy is the technological principal for both the subject and predicate devices. Application of negative pressure to an incision site that is closed via staples or sutures helps draw the incision edges together and removes fluid from the incision site. The occlusive drape of the dressing provides a negative pressure environment and protects the incision from external contamination.

At a high level, the subject device and predicate device are based on the following same technological elements:

- The dressings that are applied over the incision site in the operating room are identical. One of the following dressings may be selected by the surgeon, based on incision length and geometry:
  - The Prevena Peel & Place Dressing (cleared under K100821) which can be used for linear incisions up to 8 inches, or
  - The Prevena Customizable Dressing (cleared under K121883), which can be configured for non-linear incisions or linear incisions longer than 8 inches
- A negative pressure pump (therapy unit) is required that can provide -125 mmHg of negative pressure continuously to the dressing for a maximum of 7 days.
- The dressings are connected to the therapy unit via a disposable canister.
- Incision fluid is collected into the disposable canister
- The therapy unit provides alarms that indicate when negative pressure wound therapy may be compromised (e.g., visual and audible alarms indicating an air leak in the system or when the canister is full or when batteries are low).

The following technological differences exist between the subject and predicate devices:

- The volume and mute time has been changed for the Leak Alert and the mute time has been changed for the Low Battery Alert to minimize nuisance alerts under the new air leak threshold
- The air leak threshold has been slightly increased to allow for more air in the system before therapy unit alarms
- The labeling has been updated to reflect the proposed change in mute times

Performance Data [21 CFR 807.92(b)]

Summary of non-clinical tests conducted for determination of substantial equivalence [21 CFR 807.92(b)(1)]

The Prevena 125 Therapy Unit was evaluated to ensure conformance to design specifications following minor changes to software to reduce nuisance alerts.

The following bench tests were conducted:

- Performance testing to confirm therapy unit delivers negative pressure wound therapy within specification
- Software verification and validation testing to confirm that therapy unit performs as designed
- Battery life testing to demonstrate that changes do not affect battery life.

Summary of clinical tests conducted for determination of substantial equivalence or of clinical information [21 CFR 807.92(b)(2)]

No clinical tests were necessary. However:

- Usability testing was conducted with patient users to assess the impact of proposed labeling changes made as a result of software changes. The results demonstrated that all usability goals were met, and recommended changes to the Patient Guide have been addressed.

Conclusions drawn [21 CFR 807.92(b)(3)]

The Prevena Incision Management System and its predicate (K121883) are substantially equivalent in terms of safety, function and indications for use.